



DEPARTMENT OF THE ARMY  
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND  
504 SCOTT STREET  
FORT DETRICK, MD 21702-5012

REPLY TO  
ATTENTION OF

MCMR-RCQ

22 JAN 2004

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Command Policy, 2004-01, Communications with the Food and Drug Administration

1. References.

- a. The Code of Federal Regulations, Title 21, Food and Drugs.
- b. International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use – Good Clinical Practice: Consolidated Guideline.
- c. FDA Guidance for Industry - Formal Meetings With Sponsors and Applicants for PDUFA Products

2. Purpose. This memorandum establishes policy for recording, distribution, and filing of communications with the Food and Drug Administration (FDA) involving Surgeon General sponsored FDA-regulated products. These activities are necessary to maintain a complete regulatory file such that important information regarding FDA communications is available to required stakeholders. A lack of complete information regarding FDA communications may result in misunderstandings between the sponsor's representative and investigators. This may lead to delays in the developmental program (such as when personnel change), and a failure to appropriately respond to requests for information from the FDA with the potential for negative actions such as clinical hold on research.

3. Definitions.

- a. Formal FDA communication. Formal communications involve the exchange of signed correspondence between the FDA and the sponsor's representative (Commander, USAMMDA). Formal communications can be initiated by either the FDA or the sponsor's representative. Formal communications from the sponsor's representative include any documents submitted to the Agency along with a corresponding form such as Form FDA 1571, Form FDA 356h, Form FDA 2252. Examples of formal communications to the FDA include original IND submissions, protocol amendment, information amendments, safety reports, and annual reports.

SUBJECT: Command Policy, 2004-01, Communications with the Food and Drug Administration

Examples of formal communications from the FDA include letters of comment and advice on INDs, clinical holds and request for modifications, termination or inactive status for INDs, and letters regarding meeting on INDs. Formal communications can be sent by either party through the mail, by fax, or through a courier. USAMRMC will follow-up any fax submitted to the FDA by mailing the original as soon as possible. Additionally, meetings will be arranged with the FDA according to procedures identified in the FDA Guidance for Industry – Formal Meetings with Sponsors and Applicants for PDUFA products.

b. Informal FDA communication. Informal communications can be telephone conversations, faxes, and e-mails initiated by either the FDA or the sponsor. Informal communications occur during the normal course of drug/vaccine/device development and do not constitute a formal submission with an applicable FDA submission with cover letter and serial number to file.

#### 4. Policy.

a. The Regulatory Affairs section in the Office of Regulatory Compliance and Quality maintains records of all FDA communications involving TSG-sponsored regulated products.

b. To the extent possible, the sponsor's subject matter expert and/or medical expert for the respective product will be involved in all formal and informal communications with the FDA.

c. Formal submissions to the FDA will be maintained by the Regulatory Affairs section in the Office of Regulatory Compliance and Quality in both electronic and paper format. RCQ will provide the FDA submission form and applicable correspondence to the Commander, USAMMDA; Commander of the respective USAMRMC lab/institute; and the investigator (if the submission involves a specific protocol). Other organizations within USAMRMC (e.g., lab/institute regulatory affairs/research support office) and external agencies (e.g., CBMS) will be provided copies as applicable.

d. Informal communications with the FDA will be documented and forwarded to the regulatory file maintained in RCQ Regulatory Affairs. The enclosed diagram depicts the process and information elements to include in reporting the informal communication. A summary of the communication may be faxed to RCQ Regulatory Affairs at 301-619-4164/7803 or e-mailed to USAMRMCRegulatoryAffairs@det.amedd.army.mil. Regulatory Affairs will file the document in the regulatory file, record receipt in the RCQ

MCMR-RCQ

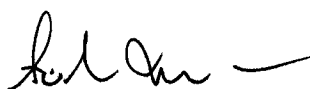
22 JAN 2004

SUBJECT: Command Policy, 2004-01, Communications with the Food and Drug Administration

Information Management System, and as applicable, coordinate with USAMMDA the identification of a suspense date for completing any FDA-requested actions. RCQ will ensure that the report of the informal communication is provided to the Commander, USAMMDA; Commander of the USAMRMC lab/institute as applicable; the investigator (if the communication involves a specific protocol); and other applicable activities, and the lab/institute regulatory affairs office. Depending on the circumstances of the communication, a follow-up confirmation of the discussion may be formally submitted to the FDA (e.g., submitted with a FDA Form 1571) to verify the sponsor's understanding of the discussion.

5. The POC for this policy is COL Jerry Pierson, Chief, Regulatory Affairs, Office of Regulatory Compliance and Quality at DSN 343-2602, commercial phone 301-619-2602, or electronic mail [jerry.pierson@det.amedd.army.mil](mailto:jerry.pierson@det.amedd.army.mil).

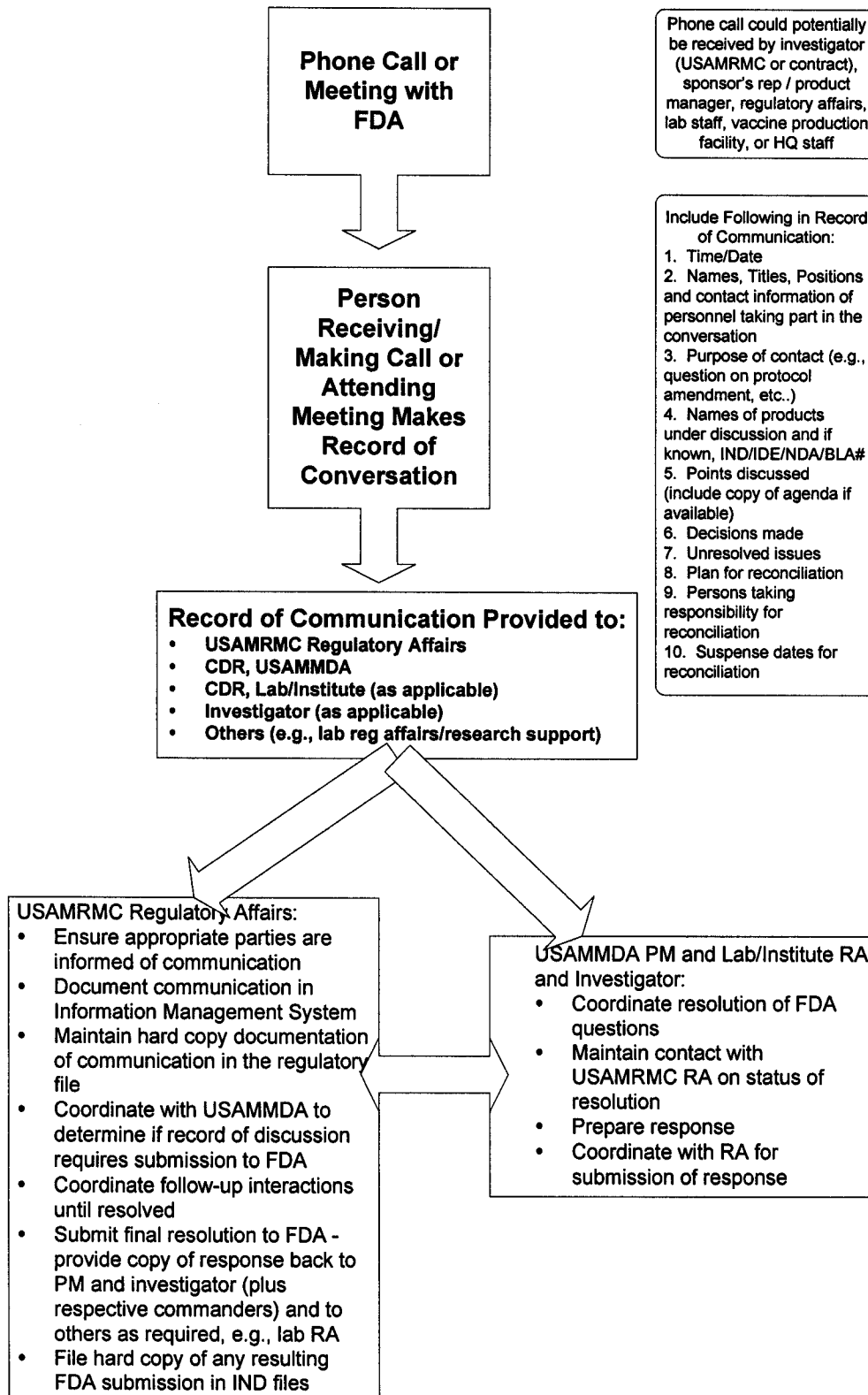
Encl



LESTER MARTINEZ-LOPEZ  
Major General, MC  
Commanding

DISTRIBUTION:  
A

## FDA Informal Communication Diagram



Encl: FDA Informal Communications Diagram

Encl